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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/494,297 01/31/00 PODBIELSKI

A P06628US0/BA

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HM22/1019

EXAMINER

SWARTZ, R

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

10/19/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/494,297	Applicant(s) Podbielski
Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26September2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*; 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on 26September2001 is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

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DETAILED ACTION

1. Please note that the Patent Examiner of your application in the PTO has changed. All communications should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (703)308-4244.
2. Applicant's Declaration under 37 C.F.R. §1.131, received 26September2001, paper#8, is acknowledged. Applicant's Response to Office Action, received 26September2001, paper#9, is acknowledged. Claims 5-18 have been canceled without prejudice or disclaimer.
3. Currently, claims 1-4 are pending and under consideration.

Drawings

4. The formal drawings submitted 26September2001 have been reviewed by the Draftsperson and approved.

Rejections Withdrawn

5. The rejection of claim 1 under 35 U.S.C. §102(a/b) as being anticipated by Podbielski et al (*Molecular Microbiology*, 31(4):1051-1064, 1999) is withdrawn in light of the Declaration. Applicant argues that the cited reference is applicant's own invention and was published less than one year prior to the instant application's filing date. The Declaration (paper#8) is presented in support of applicant's argument.

The examiner has considered applicant's argument, and finds it persuasive in light of the Declaration (paper#8).

New Rejections

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Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is directed to a protein which “is encoded by an amino acid sequence”. It is unclear what is meant by this phrase because proteins are encoded by nucleic acid sequences.

9. Claims 1 and 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid sequences designated SEQ ID NO:1 and SEQ ID NO:3 isolated from *Streptococcus pyogenes*, does not reasonably provide enablement for all nucleic acid molecules encoding all collagen-binding proteins from all other group A *Streptococcus* bacteria. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - all isolated nucleic acid molecules encoding a collagen-binding protein isolated from any group A *Streptococcus* bacteria (claim 1) and nucleic acid molecules comprising a sequence which hybridizes to SEQ ID NO:1 or SEQ ID NO:3.

The state of the prior art in nucleic acid isolation is high. However, the predictability of fulfilling the claimed invention based only upon two sequences from one species of bacteria is low.

The amount of direction or guidance present - The specification teaches only 2 nucleic acid sequences which encode collagen binding protein. The two sequences are both isolated from the same group A bacteria, *Streptococcus pyogenes*.

While the relative skill of those in the art of DNA isolation is high, the quantity of experimentation necessary to fulfill the claimed invention is also high, without a reasonable

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expectation of success. The scope of the claim (any nucleic acid molecule encoding a collagen binding protein) includes numerous structural variants because the specification places no common structural attributes to identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. The recitation of the function “collagen binding” does not convey a common structure. As such generic polynucleotide sequences that are unrelated via structure are highly variant and not conveyed by the specification at the time of filing.

Claim 4 merely recites that the nucleic acid comprises a sequences which “selectively hybridizes” to SEQ ID NO:1 or SEQ ID NO:3. The use of the phrase “selectively hybridizes” places no stringency requirements, therefore any level of hybridization fulfills this recitation, and as such again conveys little structural identity of the claimed molecule.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

11. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanski et al

(Proc. Natl. Acad. Sci., USA, 89:6172-6176, 1992).

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The claims are directed to an isolated nucleic acid molecule encoding a collagen-binding protein isolated from group A *Streptococcus* bacteria and an isolated nucleic acid molecule “comprising” SEQ ID NO:1 or SEQ ID NO:3.

The open language of the claims, “an isolated nucleic acid molecule” and “comprises” encompasses chromosomal DNA which would comprise the region encoding a collagen-binding protein. Hanski et al teach the isolation of chromosomal DNA from *Streptococcus pyogenes* (page 6173, col. 1, lines 8-10), therefore teaching the claimed invention.

Conclusion

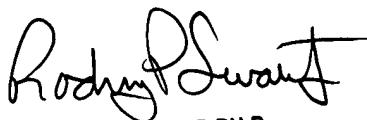
12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

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RODNEY P SWARTZ, PH.D.
PRIMARY EXAMINER

October 17, 2001